ADVANCED INFUSION

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K071532

510(k) SUMMARY – Safety and Effectiveness

Alpha Infusion Pump

FEB 19 2008

Owner:	Advanced Infusion, Inc. 920 E. University Drive, Suite D202 Tempe, Arizona 85281 (480) 768-9747 (480) 894-5288 fax
Contact:	James Christensen Vice President Operations (909) 394-4916
Date Prepared:	February 12, 2008
Trade Name:	*Alpha Infusion Pump*
Common Name:	Infusion Pump
Classification Name:	Elastomeric Infusion Pump (21 CFR 880.5725, Product Code MEB)
Predicate Devices:	K021964 – Alpha Infusion Pump and Catheters K003915 – Accufuser and Accufuser Plus
Device Description:	The Alpha Infusion Pump consists of two elastomeric chambers, which pressurize the medication. These chambers are protected in a plastic housing. A one-way check valve is provided to fill these chambers. Medication delivered from the elastomeric chambers is filtered through a 5-micron filter and held in an outflow chamber. An internal pressure regulator maintains the pressure of the medication in the outflow chamber at 6 psi in order to provide a constant flow rate through each infusion catheter inserted through the septum into the outflow chamber of the pump.
Intended Use:	The Alpha Infusion Pump is intended for the infusion of a local anesthetic into a surgical site or body cavity, post-operatively, for the relief of pain. Medication is intended to be delivered through a catheter containing a flow restriction element. The Alpha Infusion Pump is intended for use in the hospital or by an ambulatory patient.

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Technological Comparison:

The elastomeric chamber material for the Alpha Infusion Pump is being changed from medical grade polyisoprene to medical grade silicone. The silicone elastomer chosen has substantially the same material properties as the previous used polyisoprene elastomer.

Silicone is already used elsewhere in the pump for the septum, in the pressure regulator, and in the check valve. Polyisoprene will no longer be used in the Alpha Infusion Pump. Silicone elastomer chambers are also used in Accufuser and Accufuser Plus infusion pumps marketed by McKinley.

Conclusion:

The Alpha Infusion Pump with the silicone elastomer chambers is substantially equivalent to the current Alpha Infusion Pump with the polyisoprene chambers.

k071532

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2008

Mr. James Christensen
Vice President Operations
Advanced Infusion, Incorporated
466 West Arrow Highway, Unit H
San Dimas, California 91773

Re: K071532
Trade/Device Name: Alpha Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: February 6, 2008
Received: February 7, 2008

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K071532

Device Name: Alpha Infusion Pump

Indications for Use:

The Alpha Infusion Pump is intended for the infusion of a local anesthetic into a surgical site or body cavity, post-operatively, for the relief of pain. Medication is intended to be delivered through a catheter containing a flow restriction element. The Alpha Infusion Pump is intended for use in the hospital or by an ambulatory patient.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K071532